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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,580	12/09/1999	MILES B. BRENNAN	3718-3	9015

22442 7590 04/17/2002

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,580

Applicant(s)

BRENNAN ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-10,13,16,18-21,23-29,31-39,53-57,59,66-68,70,73-75,80-82,85-91,93-95,98-100,102,103 and 108-114.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,4-10,13,16,18-21,23-29,31-39,53-57,59,66-68,70,73-75,80-82,85-91,93-95,98-100,102,103 and 108-114.

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RESTRICTION AND SPECIES ELECTION

Prosecution status

1. The examiner in charge of this application has changed. The application is now being handled by Primary Examiner Stephanie Zitomer. Any inquiries regarding this and subsequent communications should be directed to Stephanie Zitomer at telephone number (703) 308-3985.

Response to applicant's election

2. Applicant's election with traverse of Group I, claims 1, 4-10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99, 102, 103 and 108-114 in paper no. 12, filed February 12, 2002, is acknowledged. The traversal is not found persuasive because the contention that Groups I and II are "closely related" is unsupportable. The Group I method requires only the administering to an animal of an MSH compound and implied measurement of body weight whereas the Group II method requires steps of measuring serum MSH level and identifying animals having MSH levels in serum of less than about 0.1 ng/ml. Furthermore, the former method is directed to causing a decrease in body weight or in rate of weight gain whereas the later method is to regulate metabolic efficiency wherein the two methods require different kinds of measurement to determine the different results in the two methods. As to Group III, the argument that the claimed composition is "not intended for use" in the method cited in the restriction is irrelevant as the chemical, structural and functional properties of the compositions are not affected by their use. Thus, they may be used in other methods. No support or explanation is given for the allegation that "the Examiner has not provided a reasonable explanation". The requirement is still deemed proper and is therefore made FINAL.

RESTRICTION

3. Further restriction of Group I to one of the following inventions is required under 35 U.S.C. 121:

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- IA1. Claims 1, 4-8, 10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99 102 and 103, drawn to a method to decrease body weight or rate of weight gain in an animal employing SEQ ID NO:2, classified in class 514, subclass 2;
 - IA2. Claims 1, 4-6, 8, 10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99, 102, 103, drawn to a method to decrease body weight or rate of weight gain in an animal employing SEQ ID NO:3, classified in class 514, subclass 2;
 - IA3. Claims 1, 4-6, 8, 10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99, 102, 103, drawn to a method to decrease body weight or rate of weight gain in an animal employing SEQ ID NO:4, classified in class 514, subclass 2;
 - IA4. Claims 1, 4-6, 8-10, 13, 16, 18-29, 31-39, 53-56, 59, 98, 99, 102, 103, drawn to a method to decrease body weight or rate of weight gain in an animal employing SEQ ID NO:1, classified in class 514, subclass 2;
 - IB1. Claims 108-114, drawn to a method to increase body weight or decrease rate of weight loss in an animal employing SEQ ID NO:5, classified in class 514, subclass 2;
 - IB2. Claims 108-114, drawn to a method to increase body weight or decrease rate of weight loss in an animal employing SEQ ID NO:6, classified in class 514, subclass 2.
4. Inventions IA1-IA4 and IB1-IB2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the function, mode of operation and effects of the methods of IA1-IA4 are diametrically opposed to those of Groups IB1-IB2 in that the former methods function to stimulate weight loss by administration of MSH or MSH agonist whereas those of the latter function to stimulate weight gain or slow weight loss by administration of an MSH antagonist.
5. The six invention Groups IA1-IA4 and IB1-IB2 are distinct invention methods wherein each is defined by a different therapeutic composition comprising a distinct amino acid sequence. Proteins having different amino acid sequences are structurally unrelated to one another and are distinct chemical compounds. These sequences are thus deemed to

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constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

6. Applicant is to elect one invention from Groups IA1-IA4 or from IB1-IB2. The claims in that Group will be examined with regard to the amino acid sequence designated for that group except as explained below in Election of Species. Nonelected sequences in multiple-sequence claims will be withdrawn from prosecution.

7. Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

ELECTION OF SPECIES

9. The provisional election of a species recited in a Markush-type group determines which claims in the elected Group will be examined, i.e., the claims that are generic to (read on) the elected species. Claims which are not generic to the elected species will be withdrawn from prosecution. If the claimed method employing the therapeutic composition comprising the elected species is searched and found patentable the search will be repeated with another of the species in the Markush group and so on unless and until a species is found to render the claimed method unpatentable over the prior art. The patentable method/species then will be identified to applicant and the unpatentable method/species will

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be rejected. Unsearched species will remain withdrawn from prosecution. See also below at paragraph 14. See MPEP 803.02 for a full explanation of Markush practice in the Patent Office.

10. Groups IA1-IA4 contain claims directed to methods employing the following patentably distinct species of therapeutic composition comprising an α -MSH analog:

multiple chemical structures thereof in claim 8, a.-k. **Applicant is required to elect a single complete (having no possible variants) chemical structure. N.B.** In Groups IA2 and IA3 the distinct amino acid sequence (SEQ ID NO:) on which restriction is based is also a species in the claim 8 Markush group. If one of these invention Groups is elected applicant is given the option of electing a different species (chemical structure) from claim 8 in place of the amino acid sequence.

11. Groups IB1 and IB2 contain claims directed to methods employing the following patentably distinct species of therapeutic composition comprising MSH antagonist:

multiple chemical structures of MSH analog in claim 112 a.-c. **Applicant is required to elect a single complete (having no possible variants) chemical structure. N.B.** In Groups IB1 and IB2 the distinct amino acid sequence (SEQ ID NO:) on which restriction is based is also a species in the claim 112 Markush group. If one of these invention Groups is elected applicant is given the option of electing a different species (chemical structure) from claim 112 in place of the amino acid sequence.

12. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims generic to (reading on) the elected species will be examined with regard to the elected species.

13. **Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

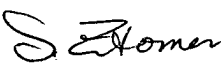
15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Examiner contact information

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.


Stephanie Zitomer, Ph.D.
April 12, 2002